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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,460	01/23/2001	Arnold J. Mandell	01561-0002-CPUS01	2132

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EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
1631	4

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/767,460	MANDELL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1 and 2 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 1 and 2 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 23 January 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .      6) Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Oath/Declaration***

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). It is noted that the instant application is not a continuation or divisional application and the provisions of 37 CFR 1.63(d)(1) does not apply.

### ***Priority***

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The instant application claims priority to Application No. 09/490701 in the first sentence of the specification which controls priority claims under 35 U.S.C. § 120. Application No. 09/490701 does not share a common inventor or disclose common subject matter with the instant

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application. It is apparent that the applicants intended to claim priority to Application No. 09/490702 and that the first sentence of the instant application contains a typographical error. Appropriate correction is required.

***Information Disclosure Statement***

3. It is brought to the applicant's attention that an Information Disclosure Statement was in the application folder of the instant application that is a statement from Application No. 09/490702. This statement is not relevant to the instant application because it does not contain the instant application number, and further because it is not accompanied by references as stated in the statement, and further because it did not refer to a prior application claimed under 35 U.S.C. § 120 that contains the cited references.

***Specification***

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The disclosure is objected to because of the following informalities: The abstract is too long.

Appropriate correction is required.

***Drawings***

6. New formal drawings are required in this application because the separate views of Figure 2 are not separately labeled. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of synthesizing or designing peptides that share a hydrophobic profile with a target polypeptide and the products of the methods, does not

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reasonably provide enablement for methods of synthesizing or designing peptides that share a physical property profile other than a hydrophobic profile with a target polypeptide and the products of the methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must make and use methods of synthesizing or designing peptides that share a physical property profile other than a hydrophobic profile with a target polypeptide and the products of the methods. For the reasons discussed below there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The specification presents guidance on page 1 that the utility of the claimed invention is to design or synthesize peptides that bind to a target polypeptide or protein. The specification presents guidance on page 6, line 6 - page 13, line 21 that spatially aligned interacting hydrophobic domains of two different peptides, polypeptides, or proteins may form hydrophobic

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bonds with sufficient strength to bind the two different peptides, polypeptides, or proteins. The specification presents guidance on page 5, line 15- page 6, line 5 that teaches away from using physical properties other than hydrophobicity when designing peptides that bind to a target polypeptide or protein.

c) The specification presents working examples of using hydrophobicity as a physical property to guide design and synthesis of peptides that bind target polypeptides or proteins. The specification does not provide guidance to use a physical property other than hydrophobicity to guide design and synthesis of peptides that bind target polypeptides or proteins.

d) The nature of the invention, design of peptides that bind a target polypeptide or protein, is complex.

e) Mandell et al. shows in the abstract and throughout that peptide ligands and their polypeptide receptors share alignment of hydrophobic regions that contribute to binding. The prior art does not show correlation of aligned physical properties other than hydrophobicity that contributes to binding of peptides and receptors.

f) The level of skill of those in the art of peptide design is high.

g) The prior art does not show a method of predicting binding of peptides to target polypeptides or proteins based on alignment of physical properties other than hydrophobicity.

h) The claims are broad in that they read on embodiments of determining binding of peptides with target polypeptides or proteins based on alignment of physical properties that are not known to correlate with binding.

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In order to practice the claimed methods, the skilled practitioner would first turn to the instant specification for guidance. However, the instant specification does not provide guidance to practice the claimed methods by use of physical properties other than hydrophobicity, and teaches away from consideration of other physical properties. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art does not provide such guidance. Finally, said practitioner would turn to trial and error experimentation to practice the full scope of the claimed invention without guidance from the specification or the prior art as to which embodiments of the claimed invention are operable. Such represents undue experimentation.

***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,560,542 in view of Sisto et al.

The claims are drawn to a method of making a retro-inverso peptide by consideration of physicochemical properties of peptide constituents.

U.S. Patent No. 6,560,542 claims a method of making peptides by consideration of physicochemical properties of peptide constituents. U.S. Patent No. 6,560,542 does not show a method of making retro-inverso peptides.

Sisto et al. shows in column 3 and throughout that retro-inversion peptides have the advantage of retention of activity and resistance to degradation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of U.S. Patent No. 6,560,542 to make retro-inversion peptides because Sisto et al. shows that such peptides have the advantage of retention of activity and resistance to degradation.

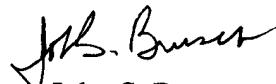
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.



John S. Brusca

Primary Examiner

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jsb

June 28, 2003